
Kayentis

Dedicated to eCOA and patient engagement

Infography: planning an oncology study with eCOA/ePRO

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The FDA has provided guidance on methodology to be used for developing and using PRO in oncology drug development programmes, and has emphasized the increased importance on patient input in clinical trials. In addition to QoL, many PRO questionnaires are used to assess complementary areas in oncology study, including: disease related symptoms (pain or fatigue), physical/social/emotional aspects, symptomatic adverse events, and satisfaction with the care provided.

Using eCOA for oncology trials can be particularly challenging because of the range of therapeutic approaches. Key components should be taken into consideration in your oncology study to ensure the success of eCOA implementation.

[To download the infography, click here:](#)

eCOA IN ONCOLOGY

WHAT TO CONSIDER WHEN PLANNING AN ONCOLOGY STUDY WITH eCOA/ePRO ?



1 COMPLEX STUDY DESIGNS Including multimodality therapy and multiple arms



Solutions and platform
instant ePRO data collection
and transmission



Customized
programming of alerts
linked to each study arm



Database set-up - randomization
online ePRO data integration
& NRG reconciliation



Earlier team work
eCOA vendor, translation
company, sponsor and authors



2 LONG-TERM DURATION Time intervals



Easy-to-use solutions and
communication tools to make
long-term studies easier for the
patient (e.g. for sending alerts,
reminders, visit schedules)



eCOA platforms, including
devices, solutions, and apps need
to be interoperable to ensure
consistency of the communication
of data workflows linked
to each patient during the different
time intervals



eCOA logistics, device reuse or site reallocation, data
management, alerts, and actions all need to be adapted
practically according to the different study time intervals



3 ADVERSE EVENTS Impact of oncology therapy on quality of life

EFFICIENT COLLECTION OF ADVERSE
EVENTS IS ESSENTIAL



eDiary adverse events/disease
symptoms collected at home



QoL
on-site visits

CLINICIAN ENGAGEMENT IS KEY



The ePRO solution/platform configuration must integrate the
investigator review: clinician engagement is key to ensure
successful eDiary completion and patient compliance

Well-implemented eCOA tools play a vital role in improving the
collection of large amounts of good quality data, improve patient
compliance and at the same time reinforce patient engagement



Learn more: <https://kayentis.com/ecoa-in-oncology>



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